

REMARKS

Status of the claims:

With the above amendments, claims 1, 8, 10-14 have been amended and claims 1-20 are pending and ready for further action on the merits. No new matter has been added by way of the above amendments. Support for the amendments to claims 1, 8, 10-14 can be found in the specification as filed. Reconsideration is respectfully requested in light of the following remarks.

Claims 1-20 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. Claims 1-8, 14-20 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 5,221,606 to Richardson (hereinafter Richardson). Claims 1-20 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over the combination of Richardson in view of U.S. Patent No. 5,464,755 to Bochner (hereinafter Bochner).

The Response is believed to overcome all of the pending Office Action rejections, and allowance of the pending claims is respectfully requested.

Title

In accordance with the Examiner's request to amend the title, Applicants herein amend the title to Devices and Methods for the Chromogenic Detection of Microorganisms.

Rejections under 35 U.S.C. §112, second paragraph

Claims 1-20 are rejected under 35 U.S.C. §112, second paragraph for allegedly being indefinite. Applicants have amended the claims to address the Examiner's specific

concerns and believe that these amendments render the rejection moot. In particular, Applicant has amended claim 1 to read “detecting and identifying”, claim 8 to read “selected from the group consisting of”, claim 10 to read “Isopropyl-β-D-thiogalactopyranoside”, claim 12 to read “rapid adsorption pad”, claim 14(c) to read “allowing”, and the last step of claim 14 to read “identify”. Withdrawal of the rejection is respectfully requested.

Rejections under 35 U.S.C. § 102

Claims 1-8 and 14-20 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated U.S. Patent No. 5,221,606 to Richardson. Applicants traverse.

The Examiner asserts that Richardson discloses chromogens adsorbed onto filter paper or a membrane to indicate the presence or absence of a particular enzyme for dipstick devices. These enzyme substrates are selectively adsorbed onto cellulose and related polymers giving intense colors which are not leached from the polymer by water. Richardson also teaches that the sample may be urine.

Applicants respectfully traverse this rejection and requests that it be withdrawn. For a reference to anticipate a claim under § 102, it must describe, either expressly or inherently, each and every element set forth in the claim. MPEP § 2131. Richardson does not describe, either expressly or inherently, each and every element set forth in independent claims 1 and 14. For example, claims 1 and 14 recite a device and method for detecting and identifying microorganisms comprising a porous body *having regions of differing pore size, said regions being associated with different chromogens specific to enzymes produced by microorganisms* (emphasis added).

The last paragraph of column 1 bridging to column 2 in Richardson is cited by the Examiner as teaching chromogens adsorbed onto a filter paper for the detection of the presence or absence of enzyme. In fact, this paragraph teaches the use of a filter paper to draw insoluble chromogens out of an aqueous solution in order to immobilize and confirm the color of the released insoluble chromogen. In other words, the use of filter paper by Richardson is for its adsorptive properties to confirm the end point of a reaction in cases when an insoluble chromogen is used. Richardson does not disclose a device or methods to detect and identify microorganisms.

Further, claims 1 and 14 recite a porous body having regions of *differing pore size* with said regions *being associated with different chromogens* specific to enzymes produced by microorganisms (emphasis added). Richardson does not teach a porous body with regions having differing pore sizes and said regions being associated with different chromogens. Rather, Richardson discloses filters that can be used to draw an insoluble chromogen from an aqueous solution.

Lastly, the Examiner states that Richardson teaches that a sample may be urine. The instant specification discloses a device that can be used for detecting microorganisms in urine, but Applicants also recognize that urine is only one of many potential substances that can be used in the present invention to identify and detect microorganisms.

Accordingly, Richardson does not teach each and every limitation of the claimed invention and withdrawal of the rejection is warranted and respectfully requested.

Rejections under 35 U.S.C. § 103

Claims 1-20 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Richardson in view of U.S. Patent No. 5,464,755 to Bochner. Applicants traverse.

The Examiner reiterated the teachings of Richardson discussed above. The Examiner stated that Richardson did not teach the use of a number of chromogenic substrates, Mg^{2+} , buffers or layered filters. The Examiner stated that Bochner teaches that urine is a sample tested as well as rapid tests that include enzymatic assays, stains, and filtration that is colorimetric. In addition, the Examiner stated that Bochner teaches multiple colorimetric substrates as well as a urinary tract pathogen test that uses multiple compartments. The Examiner stated that it would have been obvious to one skilled in the art to employ the device of Richardson to identify bacteria with chromogenic substances and include multiple chromogenic substances as taught in Bochner.

Applicants traverse.

To establish a proper case of obviousness, one must apply the *Graham v. John Deere* factors. These factors include:

- (A) *Determining the scope and contents of the prior art;*
- (B) *Ascertaining the differences between the prior art and the claims in issue;*
- (C) *Resolving the level of ordinary skill in the pertinent art; and*
- (D) *Evaluating evidence of secondary considerations.*

See *Graham v. John Deere*, 383 U.S. 1, 148 USPQ 459 (1966).

Moreover, recently in the KSR case, regarding obviousness, the Court held

Often, it will be necessary . . . to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. To facilitate review, this analysis should be made explicit. See In re Kahn, 441 F. 3d 977, 988 (CA Fed. 2006) ([R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness).

See *KSR International Co. V. Teleflex Inc. et al.* 127 S. Ct. 1727 (2007).

When the *John Deere* factors and the holding in *KSR* are considered in light of the rejection presented, one can only conclude the instantly claimed invention is non-obvious for the following reasons.

The Examiner has failed to present a *prima facie* case of obviousness. The prior art references (or references when combined) do not teach or suggest all of the claim limitations. For example, and as stated above, Richardson teaches the use of a filter paper to draw an insoluble chromogenic substrate out of an aqueous solution to identify the presence or absence of an enzyme. Richardson, therefore, does not teach a method for detecting and identifying microorganisms. Bochner fails to make up for the deficiencies of Richardson. Bochner also does not teach a device or method for detecting and identifying microorganisms. The Examiner asserts that Bochner teaches in column 7, lines 21-27 rapid tests including enzymatic assays, stains, and filtration that is colorimetric. However, in lines 33-36 of column 7, Bochner states that these approaches have significant disadvantages in that they only provide a semi-quantitative estimate of the patient's bacteriuria and do not provide an indication of the genus or species of the organism(s) present. Therefore, the goal stated by Bochner was to develop a test using nutrition-supplemented media that provided a colorimetric indication of the bacteria present. Applicants submit that Bochner teaches away from the use of enzymatic assays for detecting and identifying microorganisms as utilized by the Applicants' claimed invention. Applicants' claimed invention provides devices and methods for detecting and identifying microorganisms using enzymatic assays that do provide an indication of the specific microorganisms present in the sample. Further, the present invention does not employ the use of media supplemented with nutrients in order to stimulate the growth of

the microorganisms, but rather produces a rapid indication of the different microorganisms present without use of these growth-stimulating supplements.

Additionally, the Examiner states that Bochner teaches in column 13 the use of multiple compartments to detect and distinguish between different pathogens. According to the Examiner, the use of multiple compartments reads on the multiple layers of membranes of the current invention. However, Applicants maintain that Bochner again teaches away using multiple compartments or filters to detect and distinguish between different bacterial species. Specifically, Bochner states in column 14, lines 5-7 that the disclosed multi-compartment tests must be inoculated with pure cultures and therefore the medium is therefore *not useful for primary isolation from urine specimens* (emphasis added).

Therefore, Applicants submit that the Examiner has failed to establish a *prima facie* case of obviousness as based upon the teachings of Richardson and Bochner, one of ordinary skill in the art would have no reason to combine the references as Richardson does not teach a device or method for detecting and identifying microorganisms. Bochner does not cure that deficiency but rather teaches away from using enzymatic tests with multiple compartments to identify and differentiate between microorganisms present in a sample. Further, based upon the teaching of Bochner, one of ordinary skill in the art would have no expectation of success in developing a rapid testing device using enzymatic activity with stains, filtration that is colorimetric, and multiple layers or compartments. For at least these reasons, claims 1-20 are not obvious in view of the cited references. Applicants respectfully request reconsideration and withdrawal of these rejections.

As to the Examiner's statement that identifying bacteria with known chromogens is old and that filtering bacteria with buffers is old, Applicants point Examiner to the passage of *In re Kahn* cited by the Supreme Court in *KSR* which states:

[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.

In re Kahn, 441 F. 3d 977, 988 (Fed. Cir. 2006).

Applicants assert that Examiner's statements regarding the identification of bacteria with known chromogens and the filtration of bacteria with buffers are mere conclusory statements not supported by cited references. Therefore, the Examiner has failed to establish a *prima facie* case of obviousness for claims 1-20 and withdrawal of the rejection is warranted and respectfully requested.

CONCLUSION

With the above amendments and remarks, Applicants believe that all objections and/or rejections have been obviated. Thus, each of the claims remaining in the application is in condition for immediate allowance. A passage of the instant invention to allowance is earnestly solicited.

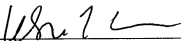
Applicants believe that no fee is necessary, however, should a fee be deemed to be necessary, the Commissioner is hereby authorized to charge any fees required by this action or any future action to Deposit Account No. 16-1435.

Should the Examiner have any questions relating to the instant application, the Examiner is invited to telephone the undersigned at (336) 607-7442 to discuss any issues.

Respectfully submitted,

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